Appl. No.10/560,889
Amdt. dated March 1, 2010

523.1006US

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings of claims in the application:

Listing of Claims:

Claims 1-37 (cancelled)

38. (Currently Amended): A method of treating migraines, cluster headaches, muscle sprains, muscle spasms, spasticity, tension headaches and tension related migraines with a topical formulation comprising applying a unit dose of a therapeutically effective amount of an active agent(s) incorporated into a **an immediate release** pharmaceutically acceptable excipient onto the skin of a human patient **at the posterior cervical area in close proximity to the brain stem**, the unit dose comprising an active agent(s) being selected from the group consisting of:

      i) an ergot alkaloid;

      ii) a skeletal muscle relaxant; or

      iii) a combination of an ergot alkaloid and a skeletal muscle relaxant;

      the unit dose providing a therapeutic effect within about 2 hours after topical administration to the human patient.

39. (Original): The method of claim 38, wherein the formulation further comprises a therapeutically effective amount of a serotonin agonist.

40. (Previously presented): The method of claim 38, wherein the therapeutically effective amount of active agent is an ergot alkaloid.

41. (Previously presented) The method of claim 38, wherein the therapeutically effective amount of active agent is a skeletal muscle relaxant.

42. (Previously presented): The method of claim 38, wherein the therapeutically effective amounts of active agents are an ergot alkaloid and a skeletal muscle relaxant.

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43. (Previously presented): The method of claim 38, wherein the formulation provides relief from a condition selected from the group consisting of migraines, cluster headaches, muscle sprains, muscle spasms, spasticity, tension headaches and tension related migraines.

44. (original): The method of claim 43, wherein the spasticity results from complication suffered in a stroke.

45. (New) The method of claim 38, further comprising incorporating the active agents into an aqueous based formulation.

46. (New) The method of claim 38, further comprising incorporating a permeation enhancer into the topical formulation.

47. (New) The method of claim 38, further comprising preparing the topical formulation in a form selected from the group consisting of a liquid, a semisolid, a solid and mixtures thereof.

48. (New) The method of claim 47, further comprising preparing the unit dose of the liquid in the form of drops, tinctures, sprays, suspensions, lotions, emulsions, dispersions or mixtures thereof.

49. (New) The method of claim 47, further comprising preparing the semisolid in the form of an ointment, cream, foam, paste, gel or mixtures thereof.

50. (New) The method of claim 47, further comprising preparing the solid is in the form of a powder, granulates, pellets, microcapsules or mixtures thereof.

51. (New) The method of claim 38, further comprising incorporating a therapeutic amount of active agent(s) into the unit dose such that the active agent(s) would provide a subtherapeutic

plasma level if orally administered, but are therapeutically effective when administered topically at the posterior cervical area.

52. (New) The method of claim 38, wherein the unit dose provides pain relief in at least 70%, preferably at least 80%, and most preferably at least 90% of a population of patients.

53. (New) The method of claim 38, wherein the ergot alkaloid is selected from the group consisting of bromocriptine, ergocristine, ergocristinine, ergotamine, ergotaminine, ergocryptine, ergocryptinine, ergocornine, ergocorninine, ergosine, ergosinine, ergonovine, ergometrinine, dihydroergotamine, lisuride, d-lysergic acid, d-isolysergic acid, lysergol, lergotrile, metergoline, methysergide, methylergonovine, pharmaceutically acceptable salts thereof, active metabolites thereof, prodrugs thereof and mixtures thereof.

54. (New) The method of claim 39, wherein the ergot alkaloid is selected from the group consisting of dihydroergotamine base, dihydroergotamine mesylate, and mixtures thereof.

55. (New) The method of claim 53, wherein the therapeutically effective amount of ergot alkaloid ranges from about 0.1 mg to about 10 mg, preferably from about 0.5mg to 6mg.

56. (New) The method of claim 38, wherein the skeletal muscle relaxant is selected from the group consisting of afloqulone, baclofen, botulin toxins, carisoprodol, chlormezanone, chlorphenesin carbamate, chlorzoxasozone, cyclobenzaprine, clonazepam, dantrolene, diazepam, eperisone, idrocilamide, inaperisone, mephenesin, mephenoxalone, methocarbamol, metaxalone, mivacurium chloride, orphenadrine, phenprobamate, pridinol mesylate, quinine, tetrazepam, thiocolchicoside, tizanidine, tolperisone, pharmaceutically acceptable salts thereof, active metabolites thereof, prodrugs thereof and mixtures thereof.

57. (New) The method of claim 38, wherein the muscle relaxant is tizanidine hydrochloride.

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58. (New) The method of claim 57, wherein the unit dose comprises from about 0.4 mg to 8 mg, preferably from about 0.2 mg to about 4 mg of tizanidine hydrochloride.

59. (New) The method of claim 38, wherein the muscle relaxant is cyclobenzaprine.

60. (New) The method of claim 38, wherein the serotonin agonist is selected from the group consisting of sumatriptan, naratriptan, eletriptan, rizatriptan, zolmitriptan, almotriptan, frovatriptan, pharmaceutically acceptable salts thereof, active metabolites thereof, prodrugs thereof and mixtures thereof.

61. (New) The method of claim 60, wherein the serotonin agonist is sumatriptan.

62. (New): The method of claim 61, wherein the unit dose comprises from about 0.5 mg to about 200 mg sumatriptan.

63. (New) The method of claim 62, wherein the unit dose comprises from about 5 mg to 50 mg sumatriptan.

64. (New) The method of claim 38, further comprising incorporating one or more additional active agents into the topical formulation.

65. (New) The method of claim 38, further comprising incorporating one or more ingredients into the topical formulation selected from the group consisting of ethoxydiglycol, water, glycerine, C12-15alkyl benzoate, glyceryl stearate, dimethicone, cetearyl alcohol, cetearyl glucoside, polyacrylamide, cetyl alcohol, magnesium aluminum silicate, xanthan gum, aloe vera (aloe barbadensis), tocopheryl acetate (vitamin E acetate), prunus amygadalus amara (bitter almond) kernel oil, vitis vinifera (grape) seed extract, triticum vulgare (wheat) germ oil, retinyl palmitate (vitamin A palmitate), ascorbyl palmitate (vitamin C palmitate), pro-lipo multi-emulsion liposomic system, tetrasodium EDTA, phenoxyethanol, and sodium hydroxymethylglycinate.

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66. (New) The method of claim 38, wherein the active agents comprise a serotonin agonist is selected from the group consisting of sumatriptan, naratriptan, eletriptan, rizatriptan, zolmitriptan, almotriptan, frovatriptan, pharmaceutically acceptable salts thereof, active metabolites thereof, prodrugs thereof and mixtures thereof; and a skeletal muscle relaxant selected from the group consisting of afloqulone, baclofen, botulin toxins, carisoprodol, chlormezanone, chlorphenesin carbamate, chlorzoxasozone, cyclobenzaprine, clonazepam, dantrolene, diazepam, eperisone, idrocilamide, inaperisone, mephenesin, mephenoxalone, methocarbamol, metaxalone, mivacurium chloride, orphenadrine, phenprobamate, pridinol mesylate, quinine, tetrazepam, thiocolchicoside, tizanidine, tolperisone, pharmaceutically acceptable salts thereof, active metabolites thereof, prodrugs thereof and mixtures thereof.

67. (New) The method of claim 38, wherein the active agents comprise an ergot alkaloid selected from the group consisting of bromocriptine, ergocristine, ergocristinine, ergotamine, ergotaminine, ergocryptine, ergocryptinine, ergocornine, ergocorninine, ergosine, ergosinine, ergonovine, ergometrinine, dihydroergotamine, lisuride, d-lysergic acid, d-isolysergic acid, lysergol, lergotrile, metergoline, methysergide, methylergonovine, pharmaceutically acceptable salts thereof, active metabolites thereof, prodrugs thereof and mixtures thereof; and a skeletal muscle relaxant selected from the group consisting of afloqulone, baclofen, botulin toxins, carisoprodol, chlormezanone, chlorphenesin carbamate, chlorzoxasozone, cyclobenzaprine, clonazepam, dantrolene, diazepam, eperisone, idrocilamide, inaperisone, mephenesin, mephenoxalone, methocarbamol, metaxalone, mivacurium chloride, orphenadrine, phenprobamate, pridinol mesylate, quinine, tetrazepam, thiocolchicoside, tizanidine, tolperisone, pharmaceutically acceptable salts thereof, active metabolites thereof, prodrugs thereof and mixtures thereof.